

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

MAR 12 2002

(use many sheets as necessary)

Sheet

1

of

4

COMPLETE IF KNOWN

Application Number	10/010,678
Filing Date	December 7, 2001
First Named Inventor	G.J. Gormley et al.
Group Art Unit	1614
Examiner Name	V. Kim
Attorney Docket Number	19109DE

RECEIVED
MAR 15 2002
EACH CENTER 1600/2900

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code (if known)		
aa		4,377,584		RASMUSSEN et al.	03/22/1983
aa		4,760,071		RASMUSSEN et al.	07/26/1988
aa		4,396,615		PETROW et al.	08/02/1983
aa		5,175,155		JUNIEWICZ et al.	12/29/1992
aa		4,684,635		ORENTREICH et al.	08/04/1987
aa		4,885,289		BREUER et al.	12/05/1989
aa		5,053,403		ORENTREICH et al.	10/01/1991
aa		5,228,431		GIARETTO	07/20/1983
aa		5,571,817		RASMUSSEN et al.	11/05/1996
aa		5,407,944		GOLDMAN	04/18/1995
aa		5,567,708		RASMUSSEN et al.	10/22/1996
aa		5,849,764		GOULET et al.	12/15/1998
aa		5,846,976		BATCHELOR et al.	12/08/1998
aa		5,795,882		BISHOP et al.	08/18/1998
aa		5,780,437		GOULET et al.	07/14/1998
aa		5,843,953		GRAHAM et al.	12/01/1998
aa		5,777,134		BAKSHI et al.	07/07/1998
aa		5,756,507		GOULET et al.	05/26/1998
aa		5,730,964		WALDSTREICHER et al.	03/24/1998
aa		5,708,001		ANDREWS et al.	01/13/1998

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Office	Number	Kind Code (if known)		
aa			EP 0 004 949		Merck & Co., Inc.	10/31/1979
aa			EP 0 155 096		Merck & Co., Inc.	09/18/1985
aa			EP 0 285 382		Merck & Co., Inc.	10/05/1988
aa			Canada 1,302,277		Merck & Co., Inc.	06/02/1992
aa			WO 92/02225		The Upjohn Company	02/20/1992

Examiner Signature

Date Considered

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609.

Draw line through citation if not in conformance and not considered.

Include copy of this form with next communication to applicant.

Computer generated form "IDS Form" (IDS Folder), Merck & Co., Inc. 10/05/2001

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE

STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet

2

of

4

COMPLETE IF KNOWN

Application Number	10/010,678
Filing Date	December 7, 2001
First Named Inventor	G.J. Gormley et al.
Group Art Unit	1614
Examiner Name	V. Kim
Attorney Docket Number	19109DE

TECH CENTER 1600/2900

MAR 15 2002

RECEIVED

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code (if known)		
		5,610,162		WITZEL et al.	03/11/1997
		5,595,996		GRAHAM et al.	01/21/1997
		5,525,608		ADAMS et al.	06/11/1996
		5,512,555		WALDSTREICHER	04/30/1996
		5,438,061		BERGMAN et al.	08/01/1995
		5,480,889		GOLDMAN	01/02/1996
		5,658,922		DURETTE et al.	08/19/1997
		5,763,361		HARRIS et al.	06/09/1998
		5,741,795		ASTER et al.	04/21/1998
		5,739,137		DURETTE et al.	04/14/1998
		5,719,158		DURETTE et al.	02/17/1998
		5,543,417		WALDSTREICHER	08/06/1996
		4,788,218		Tanabe et al.	11/29/1988
		4,689,345		Kasha et al.	08/25/1987
		5,824,686		Gormley et al.	10/20/1998
		5,981,543		Gormley et al.	11/09/1999
		4,760,071		Rasmussen et al.	07/26/1988
		5,152,997		Ebert et al.	10/06/1992

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Office	Number	Kind Code (if known)		
			WO 93/23039		Merck & Co., Inc.	11/25/1993
			EP 0 285 383		Merck & Co., Inc.	03/30/1988
			EP 0 572 166		Merck & Co., Inc.	05/19/1993
			EP 0 294 937		Ono Pharmaceuticals Co., Ltd.	05/06/1988
			WO 93/23050		Merck & Co., Inc.	11/25/1993
			WO 93/23048		Merck & Co., Inc.	11/25/1993
			WO 93/23051		Merck & Co., Inc.	11/25/1993

Examiner
SignatureDate
Considered

6/3/02

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609.

Draw line through citation if not in conformance and not considered.

Include copy of this form with next communication to applicant.

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use many sheets as necessary)

Sheet

3

of

4

Application Number

10/010,678

Filing Date

December 7, 2001

First Named Inventor

G.J. Gormley et al.

Group Art Unit

1614

Examiner Name

V. Kim

Attorney Docket Number

19109DE

TECH CENTER 1600/2900

MAR 15 2002

RECEIVED

OTHER NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
	AA	Gormley et al., J. Clin. Endo. Metab., Vol. 70, pp. 1136-1141 (1990), "Effects of finasteride (MK-906), a 5alpha-reductase inhibitor, on circulating androgens in male volunteers"
	AB	Transcript, WNBC-TV, News 4 NY Live at Five, Nov. 29, 1993
	AC	Diani et al., J. Clin. Endo. Metab., Vol. 74, pp. 345-350 (1992), "Hair growth effects on oral admin. of finasteride, a steroid 5alpha-reductase inhibitor ..."
	AD	Imperato-McGinley et al., J. Clin. Endoc. Metab., Vol. 70, pp. 777-782 (1990), "The 5-alpha reductase inhibitor finasteride comparison of male pseudohermaphrodites ..."
	AE	Bingham et al., J. Endoc., Vol. 57, pp. 111-121 (1973), "The metabolism of testosterone by human male scalp skin"
	AF	Stoner et al., Prostate, Vol. 22, pp. 291-299 (1993), "Finasteride (MK-906) in the treatment of benign prostatic hyperplasia"
	AG	Stoner et al., J. Urol., Vol. 147, pp. 1298-1302 (1992), "The clinical effects of a 5-alpha-reductase inhibitor, finasteride, on benign prostatic hyperplasia"
	AH	Sudduth et al., Pharmacotherapy, Vol. 13, pp. 309-325 (Jul-Aug 1993), "Finasteride: The first 5-alpha-reductase inhibitor"
	AI	Gormley et al., New Eng. J. Med., Vol. 327, pp. 1185-1191 (1992), "The effect of finasteride in men with benign prostatic hyperplasia"
	AJ	Matzkin et al., Clin. Endocrin., Vol. 37, pp. 432-436 (1992), "Prolonged treatment with finasteride (a 5-alpha-reductase inhibitor) does not affect bone density and metabolism"
	AK	McConnell et al., J. Clin. Endoc. Metab., Vol. 74, pp. 505-508 (1992), "Finasteride, an inhibitor of 5alpha-reductase, suppresses prostatic dihydrotestosterone in men ..."
	AL	McConnell et al., J. Urol., Vol. 143, No. 4, Suppl., p. 267A (1990), "The effects of low-dose finasteride (MK-906) on prostatic androgen levels in men with benign prostatic ..."
	AM	Vermeulen et al., Eur. Urol., Vol. 20, Supp. 1, pp. 82-86 (1991), "Hormonal effects of 5alpha-reductase inhibitor (Finasteride) ..."
	AN	Vermeulen et al., Prostate, Vol. 14, pp. 45-53 (1989), "Hormonal effects of an orally active 4-azasteroid inhibitor of 5-alpha-reductase in humans"
	AO	Metcalf et al, Trends Pharmacol. Sci., Vol. 10, pp. 491-495 (1989), "Inhibitors of steroid 5-alpha-reductase in benign prostatic hyperplasia, male pattern baldness and acne"

Examiner
SignatureDate
Considered

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609.

Draw line through citation if not in conformance and not considered.

Include copy of this form with next communication to applicant.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE

STATEMENT BY APPLICANT

MAR 1 2 2002

(use as many sheets as necessary)

PATENT & TRADEMARK OFFICE

4

of

4

Application Number 10/010,678

Filing Date December 7, 2001

First Named Inventor G.J. Gormley et al.

Group Art Unit 1614

Examiner Name V. Kim

Attorney Docket Number 19109DE

COMPLETE IF KNOWN

TECH CENTER 1600/2900

MAR 1 5 2002

RECEIVED

OTHER NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
	AP	Tempany et al., Prostate, Vol. 22, pp. 39-42 (1993), "The influence of finasteride on the volume of the peripheral and periurethral zones of the prostate ..."
	AQ	Muller et al., Small Animal Dermat., 2nd ed., (1976), pp. 491-501, "Alopecias"
	AR	Gormley et al., Prob. in Urology, Vol. 5, No. 3, pp. 436-440 (1991), "The role of 5alpha-reductase inhibitors in the treatment of benign prostatic hyperplasia"
	AS	Rittmaster et al., J. Clin. Endoc. Metab., Vol. 65, No. 1, pp. 188-193 (1987), "The effects of N,N-diethyl-4-methyl-3-oxo-4-aza-5alpha-androstane-17beta-carboxamide, a 5alpha-reductase inhibitor and antiandrogen, on the development of baldness ..."
	AT	Mellin et al., J. Steroid Biochem. Mol. Biol., Vol. 44, No. 2, pp. 121-131 (1993), "Azasteroids as inhibitors of testosterone 5alpha-reductase in mammalian skin"
	AU	Stoner, J. Steroid Biochem. Mol. Biol., Vol. 37, no. 3, pp. 375-378 (1990), "The clinical development of a 5alpha-reductase inhibitor, finasteride"
	AV	Dallob, J. Clin. Endoc. Metab., Vol. 79, No. 3, pp. 703-706 (1994), "The effect of finasteride, a 5alpha-reductase inhibitor, on scalp skin testosterone and dihydrotestosterone concentrations ..."
	AW	Waldstreicher et al., J. Invest. Derma., Vol. 102(4), p. 615 (1994), Item No. 549, "Effects of finasteride on dihydrotestosterone content of scalp skin in men with male pattern baldness"
	AX	Shupack et al., Int. J. Dermat. 31(10) 1993, pp. 701-706, "Status of medical treatment for androgenetic alopecia"
	AY	Kaufman et al., J. Invest. Derma. 102(4), 1994, p. 615, Item No. 550, "A 12 month pilot clinical study of finasteride on men with male pattern baldness"
	AZ	Rhodes et al., J. Clin. Endocrin. & Metab., 79(4), 1994, pp. 991-996, "The effects of finasteride (Proscar) on hair growth, hair cycle stage, and serum testosterone and dihydrotestosterone in adult male and female stump-tail macaques (Macaca arctoides)"
	BA	Steiner, Clin. Pharm. (USA) 12(1) 1993, pp. 15-23, "Finasteride: A 5alpha-reductase inhibitor"
	BB	Gormley, Drug Research Reports: The Blue Sheet, Vol. 35, No. 20, 1992, pp. 6-7, "Proscar in clinicals for chemoprevention following prostatectomy"
	BC	Sawaya et al., Dermatol. Clin. (USA) 11(1) 1993, pp. 65-72, "The antiandrogens: when and how they should be used"
	BD	Simpson, J. Derm. Treat. (1989), pp. 107-109, "The management of androgenic alopecia in women"

Examiner Signature

Date Considered

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609.
Draw line through citation if not in conformance and not considered.
Include copy of this form with next communication to applicant.